

CLAIMS

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1. A pharmaceutical formulation comprising human parathyroid hormone at a concentration of or above 0.3 mg/ml to 10 mg/ml; a pharmaceutically acceptable buffer having a pH from 4 to 6, and at least one tonicity modifier.
2. The formulation according to claim 1 wherein the said human parathyroid hormone is human recombinant parathyroid hormone.
- 10 a 3. The formulation according to claim 1 ~~to 2~~ wherein the said human parathyroid hormone is full-length parathyroid hormone.
- a 4. The formulation according to ~~any one of claims 1 to 3~~ wherein the concentration of the said human parathyroid hormone is from 0.3 mg/ml to 5 mg/ml.
- 15 5. The formulation according to claim 4 wherein the concentration of the said human parathyroid hormone is from 1 mg/ml to 3 mg/ml.
- a 20 6. The formulation according to ~~any one of claims 1 to 5~~ wherein the said pharmaceutically acceptable buffer is a citrate buffer at a concentration from 5 to 20 mM.
- a 25 7. The formulation according to ~~any one of claims 1 to 6~~ wherein the said pharmaceutically acceptable buffer has a pH between 5 and 6.
- a 8. The formulation according to ~~any one of claims 1 to 7~~ wherein the said tonicity modifier is sodium chloride and/or mannitol.
- 30 9. The formulation according to ~~any one of claims 1 to 8~~ comprising 1 to 3 mg/ml parathyroid hormone, 2 to 5 mg/ml NaCl, 20 to 50 mg/ml mannitol, 5 to 10 mM citrate buffer at a pH between 4 and 6, and optionally a preservative.

a 10. The formulation according to ~~any one of claims 1 to 9~~ in liquid form.

a 11. The formulation according to ~~any one of claims 1 to 9~~ in lyophilized form.

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a 12. A process for the preparation of a pharmaceutical formulation according to ~~any one of claims 1 to 11~~, comprising dissolving human parathyroid hormone, to a concentration from 0.3 to 10 mg/ml, and at least one tonicity modifier, in a pharmaceutically acceptable buffer having a pH between 4 and 6.

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a 13. A pharmaceutical formulation according to ~~any one of claims 1 to 11~~ ^{claim 1} for use in the treatment or prevention of bone disorders.

a 14. A pharmaceutical formulation according to ~~any one of claims 1 to 11~~ for use in the
15 treatment or prevention of osteoporosis.

20 15. Use of parathyroid hormone at a concentration from 0.3 to 10 mg/ml, in the manufacture of a pharmaceutical formulation for the treatment or prevention of bone disorders, said pharmaceutical formulation in addition comprising a pharmaceutically acceptable buffer having a pH between 4 and 6, and at least one tonicity modifier.

16. The use according to claim 15 for the treatment or prevention of osteoporosis.

a 25 17. A method for treatment or prevention of bone related disorders which comprises administering to a mammal, including man, in need of such treatment or prevention an effective amount of a formulation according to ~~any one of claims 1 to 11~~.

18. The method according to claim 17 for treatment or prevention of osteoporosis.

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